20. (Amended) The intervertebral implant according to claim 1, wherein the bone or bone-derived implant comprises animal bone.

21. (Amended) The intervertebral implant according to claim 20, wherein the bone or bone-derived implant comprises human bone.

22. (Amended) The intervertebral implant according to claim 1, wherein the surface of the bone or bone-derived implant is demineralized.

Please cancel Claims 3, 18 and 19 without prejudice.

REMARKS

Claims 1-27 are pending in the application with Claims 10-17 and 25-27 having been withdrawn from consideration. By this Amendment, applicants have cancelled Claims 3, 18 and 19 and amended Claims 1, 2, 20, 21 and 22.

In the Office Action mailed April 19, 2002, the Examiner has objected to the drawings as failing to comply with 37 CFR 1.84(p)(5) because they do not include a reference to "37" for slot on page 17, line 7. Applicants have amended the specification to correctly refer to the slot as "32" and respectfully request this objection be withdrawn.

The Examiner has objected to the disclosure because of several informalities. The first asserted informality is that "reference character "32" has been used to designate both "slot," line 19 of page 13 and "bore," line 19 of page 17. Applicants believe the Examiner meant to refer to line 7 of page 17 where reference character "32" is used to designate "bore", as there is no reference to "bore" on line 19 of page 17. As noted above with respect to the objection to the drawings, applicants have amended the specification

to correctly refer to the slot as "32" and the bore as "34" and respectfully request this objection be withdrawn.

The Examiner has also objected to the specification on the basis that the recitation of implant "10" on page 19, lines 11 and 16 should be "100", and the recitation of throughbore "34" on page 20, line 3, should be "134". Applicants have amended the specification to correct these typographical errors and respectfully request withdrawal of the foregoing objections.

The Examiner has next objected to Claim 3 on the grounds it is in improper dependent form for failing to further limit the subject matter of a previous claim. Claim 3 has been cancelled, thus obviating this rejection.

Claims 2 and 3 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants have amended Claim 2 for clarification and cancelled Claim 3. Accordingly, withdrawal of the rejection of Claims 2 and 3 under 35 U.S.C. § 112 is respectfully requested.

Claims 1-7 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,683,463 ("Godefroy et al."). The examiner applies Godefroy et al. as follows:

> ...Fig. 6 shows a "substantially" cylindrical body having at least two tabs **16**, **14** longitudinally displaced and are at least less *or equal* to the maximum diameter of the body. It can also be seen there is at least one throughbore **9**. Fig. 1 shows a body portion with one end having an installation slot **24** and a bore **23** between the slot.

Nowhere does Godefroy et al. disclose a bone or bone-derived intervertebral implant having at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs being configured for retention within a preformed recess within the vertebral body. Rather, Godefroy et al. disclose intervertebral implants made of metal or a rigid synthetic material (see specification, column 2, line 38), having "ribs" 13, 14 and 16 which function in this implant to "...prevent both axial movement in translation and rotation of the implant, the teeth becoming embedded in the vertebrae" (Godefroy et al., column 2, lines 57-61). In contrast, the tabs of applicants' intervertebral implant are retained within a preformed recess within the vertebra, permitting access to soft or cancellous bone.

Thus nothing in Godefroy et al. would lead one skilled in the art to applicants' intervertebral implant, which is made of bone or bone-derived material and has at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs being configured for retention within a preformed recess within the vertebral body. As one skilled in the art would recognize, there are significant differences between using metal or rigid synthetic materials as implants compared with natural bone and bone-derived materials. Moreover, there are significant differences between having tabs or fins which cut into the vertebral plate, as in Godefroy et al., and having a preformed recess in the vertebrae which retains the tabs of an implant and permits access to cancellous or soft bone which occurs with applicants' invention. Specifically, these differences include, but are not limited to, the following:

1. bone from the vertebrae adjacent to an intervertebral implant will grow onto

the surface of a bone or bone-derived implant, something that will not occur with a metal or synthetic material;

2. a bone or bone-derived implant will eventually be replaced by the natural bone tissue from the recipient of the implant and there will be thus less stress-shielding compared with a metal or synthetic implant. Stress shielding refers to the fact that a metal implant will carry stress rather than the adjacent bone, thus the bone in contact with the metal implant will not be as strong in carrying loads or when placed under stress;

3. should the implant need to be removed for any reason, a bone or bone-derived implant will be easier to remove, with less removal of additional vertebral tissue, as the removal of a metal implant will require the removal of additional healthy vertebral tissue;

4. the placement of the tabs into the preformed recess in the vertebrae permit a much more predictable placement of the implant than the cutting fins of Godefroy et al., which will wedge into the vertebral plate. Moreover, during the process of forming the preformed recess, weak spots in the vertebrae may be identified, and the resulting implant will be much better suited for bearing weight;

5. the preformed recess permits access of the implant to cancellous or "soft" bone tissue, where the majority of regenerative bone cells are located, thus permitting enhanced fusion of the implant with the adjacent vertebrae.

In view of the foregoing, applicants believe that the invention of their amended claims is not anticipated by, and nonobvious, over Godefroy et al. Therefore, withdrawal of the rejection of Claims 1-7 and 9 under 35 U.S.C. §102(b) is respectfully requested.

The Examiner has next rejected Claims 1-5, 8, 9, 18, 19, 21 and 24 as being

anticipated by U.S. Patent No. 6,290,724 ("Marino") under 35 U.S.C. §102(e). According to the Examiner, Marino teaches the following:

> ...Marino shows (Fig. 1A) a "substantially" cylindrical body with at least two tabs 36 longitudinally placed from the two ends of the vertebral implant. The use of "substantially cylindrical body" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. It can be seen that the tabs are radially spaced that a first tab is approximately 180° from a second tab on the opposite side. It can also be seen that there is a throughbore **42** which is perpendicular to the longitudinal axis and radially spaced from the tabs. The tabs have a width less than or *equal* to the maximum diameter of the body. Marino discloses the implant is formed from a biocompatible material, such as human bone, col. 6, lines 31-42.

The Examiner equates the "tabs" of the implant of Claim 1 with "anchoring fins" 36 of the Marino intervertebral insert.

Nowhere does Marino disclose an intervertebral implant having at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs being configured for retention within a preformed recess within the vertebral body. Rather, Marino discloses, as shown in Fig. 7, that when intervertebral insert 23 is installed (by being rotated, or cammed, into place), substantially the entire body of each anchoring fin 36 engages the vertebral endplates.

As noted above with respect to Godefroy et al., applicants' tabs do not cut into the vertebral end plate but, instead, are retained within a recess within the vertebral body where they have access to soft or cancellous bone.

Moreover, applicants respectfully submit that the fins of Marino must be made of some material besides bone or bone-derived materials, as they are too thin and would be too fragile to cut into bone were they themselves made of bone. Accordingly, the insert of Marino could not function as intended were its insert, including its fins, made of bone.

Thus nothing in Marino would lead one skilled in the art to applicants' intervertebral implant, which has at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs being configured for retention within a preformed recess defined within the vertebral body. As noted above with respect to Godefroy et al., one skilled in the art would recognize the significant differences between having tabs or fins which cut into the vertebral plate and applicants' preformed recess in the vertebrae which will permit access to cancellous or soft bone. These differences include the fact that the tabs of applicants' implant permit a much more predictable placement of the implant in the preformed recess in the vertebra than the cutting fins of Marino, which will wedge into the vertebral plates. Moreover, the use of a preformed recess as set forth in applicants' claims will permit access of the implant to cancellous or "soft" bone tissue, where the majority of regenerative bone cells are located, thus permitting enhanced fusion of the implant with the adjacent vertebrae.

In view of the foregoing, applicants believe that the invention of their amended claims is not anticipated by, and nonobvious, over Marino. Therefore, withdrawal of the rejection of Claims 1-5, 8, 9, 18, 19, 21 and 24 under 35 U.S.C. §102(e) is respectfully requested.

The examiner has rejected Claim 20 as obvious under 35 U.S.C. §103(a) over

Marino in view of U.S. Patent No. 5,676,146 ("Scarborough"). The examiner applies these disclosures as follows:

> ...Marino is explained supra. However, Marino does not disclose the use of animal bone for the implant. Scarborough teaches to use animal bone for an implant, col. 2, lines 13-15 and for vertebral repair, col. 3, lines 11-22. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Scarborough in the implant of Marino in order to provide a radiolucent material for easier tracking the implant after implantation.

Dependent Claim 20 incorporates therein all the limitations of its base independent claims. As noted above with respect to the 35 U.S.C. §102(e) rejection, Marino nowhere discloses or suggests an intervertebral implant having at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs being configured for retention within a preformed recess defined within the vertebral body. Rather, Marino discloses that when its intervertebral insert is installed (by being rotated, or cammed, into place), substantially the entire body of each anchoring fin engages the vertebral endplates.

Scarborough fails to remedy the deficiencies of Marino. Scarborough is directed to surgical implants containing radiopaque markers which permit the determination of the position and/or orientation of the implant following surgical implantation. There simply is no teaching or suggestion in Scarborough that its implant should have tabs which are rotated into a preformed recess within the vertebral body.

Accordingly, neither Marino nor Scarborough, alone or in combination, render

Claim 20 obvious. Withdrawal of the rejection of Claim 20 is therefore respectfully requested.

The examiner has next rejected Claim 22 as obvious under 35 U.S.C. §103(a) over Marino in view of Lewandrowski et al. The Examiner applies these disclosures as follows:

> ...Marino is explained supra. However, Marino does not disclose the surface is demineralized. Lewandrowski et al. teach that demineralization enhances bone osteoinductive properties, p.365. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Lewandrowski et al. in the implant of Marino in order to provide a prosthesis capable of stabilizing the vertebrae while stimulate bone ingrowth.

As noted above, nowhere does Marino disclose or suggest an intervertebral implant having at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs being configured for retention within a preformed recess defined within the vertebral body. Rather, Marino discloses that when its intervertebral insert is installed (by being rotated, or cammed, into place), substantially the entire body of each anchoring fin engages the vertebral endplates.

Lewandrowski et al. fails to remedy the deficiencies of Marino. Lewandrowski et al. is directed to the kinetics of cortical bone demineralization. There simply is no teaching or suggestion in Lewandrowski et al. that such demineralized bone could be utilized with a vertebral implant having tabs which are rotated into preformed recess formed within the vertebral body.

Accordingly, neither Marino nor Lewandrowski et al., alone or in combination, render Claim 22 obvious. Withdrawal of the rejection of Claim 22 is therefore respectfully requested.

The examiner has rejected Claim 23 as obvious under 35 U.S.C. §103(a) over Marino in view of U.S. Patent No. 5,445,639 ("Kuslich et al."). The Examiner applies these disclosures as follows:

> ...Marino is explained supra. Marino discloses forming a core and the implant is positioned by rotating, col. 14, lines 12-26. Marino also discloses implants and the vertebral space that the implant engages are often matched with respect to one another, col. 4, lines 10-24. However, Marino does not disclose the step of forming a stepped bore in a portion of the vertebrae. Kuslich et al. teach to bore areas for vertebral implants with progressively increased blades that can be interpreted to be a stepped bore form, col. 7, lines 55-66. Fig. 17 shows an enlarged chamber or stepped bore. Kuslich also teaches the stepped bore can be used for dowels or tabs. It would have been obvious to one of ordinary skill in the art to use the method of boring vertebrae in a stepped fashion as taught by Kuslich et al. for inserting the implant of Marino in the implanting procedure in order to provide a ready-made chamber that would not require any forceful rotation or positioning.

As noted above, nowhere does Marino disclose or suggest an intervertebral implant having at least two tabs extending radially outward from the substantially cylindrical body portion of the implant, said tabs being configured for retention within a preformed recess defined within the vertebral body. In fact, the Examiner admits in the Office Action that "Marino does not disclose the step of forming a stepped bore in a portion of the vertebrae" (see page 6 of the Office Action).

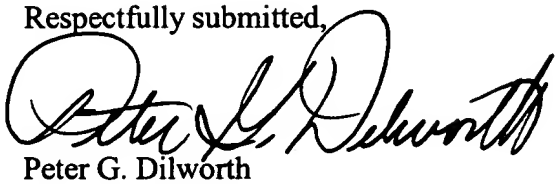
Kuslich et al. fails to remedy the deficiencies of Marino. Kuslich et al. is directed to a surgical tool capable of cutting into contiguous vertebrae to form a chamber. Contrary to the Examiner's assertion, Kuslich et al. does not refer to tabs. While Kuslich et al. teaches that such a chamber can receive a dowel for dowel-type interbody fusion, there simply is no teaching or suggestion in Kuslich et al. of applicants' intervertebral implant, which has tabs which are rotated into preformed recesses formed within the vertebral body.

Accordingly, neither Marino nor Kuslich et al., alone or in combination, render Claim 23 obvious. Withdrawal of the rejection of Claim 23 is therefore respectfully requested.

Finally, the Examiner has rejected Claims 1, 2, 4, 6, 18, 19 and 24 under the judicially created doctrine of obviousness-type double patenting over Claims 1-3, 6, 10, 16 and 23 of copending U.S. Application Serial No. 09/328,283. As noted by the Examiner, this rejection can be overcome by a terminal disclaimer in compliance with 37 C.F.R. 1.321 (c). A terminal disclaimer is being filed with and accompanies this Amendment in order to overcome this rejection. Accordingly, withdrawal of the rejection of Claims 1, 2, 4, 6, 18, 19 and 24 under the judicially created doctrine of obviousness-type double patenting is warranted and such is respectfully requested.

In view of the foregoing remarks, early and favorable consideration of the claims of the application is respectfully requested.

Respectfully submitted,



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AMENDED SPECIFICATION MARKED TO SHOW CHANGES

Please replace the text beginning on the top of page 17 with the following:

--... enlarged portion G of bore E. Implant 10 is subsequently rotated approximately 90° such that tabs 14 and 16 rotate into enlarged portion G. As noted above, retaining surfaces 22a and 22b on tab 14 and retaining surfaces 24a and 24b on tab 16 engage edges of enlarged portion G of bore E and prevent expulsion of the implant from between the adjacent vertebrae A and B. It should be noted that the entire procedure may be accomplished without any substantial or excessive distraction between adjacent vertebrae. While the present disclosure provides installation slot [37] 32 and bore [32] 34 for receipt of an installation device, it is within the contemplated scope of the present disclosure to provide implant 10 with other structure to allow insertion and rotation of the implant by various insertion tools.--

Please replace the paragraph beginning on line 6 of page 19 with the following:

--Referring now to FIGS. 25-28, there is disclosed another embodiment of an intervertebral implant which includes specific wedging structure to prevent the implant from moving longitudinally within a bore. Implant 100 generally includes a cylindrical body portion 102 having a throughbore 104 formed therein. Similar to previous embodiments, implant 100 is provided with an installation slot 106 and a bore 108 extending between installation slot 106 and throughbore 104. Implant 100 also includes a pair of radially extending first anterior tabs 110, 112 and a pair of radially extending second tabs 114, 116. As shown, first tabs 110 and 112 have curved wedge surfaces 118, 120. Similarly, second tabs 114 and 116 also include curved wedge surfaces 122 and

124. Wedge surfaces 118 and 120 of first tabs 110 and 112 curve away from a first end 126 of implant 100 and wedge surfaces 122, 124 of second tabs 114 and 116 curve away from a second end 128 of implant 100. The provision of wedge surfaces on the tabs provides a range of camming contact with the interior of a stepped bore drilled in adjacent vertebrae to thereby prevent expulsion of the implant.--

Please replace the text beginning on the top of page 20 with the following:

--... structure which, upon rotation of the implant, cams the implant into position within a stepped bore. Specifically, intervertebral implant 130 includes a cylindrical body portion 132 having a throughbore 134 formed therethrough. An installation slot 136 may be provided along with a bore 138 extending between installation slot 136 and throughbore 134. Implant 130 additionally includes first tabs 140 and 142 formed adjacent first end 144 and second tabs 146 and 148 formed adjacent a second end 150. As illustrated, first tabs 140 and 142 as well as second tabs 146 and 148 have a generally, progressively curved shape such as a spline shape or one defined by a polynomial-defined curve. Thus, first tabs 140, 142 include progressive camming surfaces 152, 154. Second tabs 146 and 148 include progressive camming surfaces 156 and 158. Implant 130 may be formed in a manner similarly described above with respect to implant 10.--

AMENDED CLAIMS MARKED TO SHOW CHANGES

1. (Amended) [An] A bone or bone-derived intervertebral implant comprising:

a substantially cylindrical body portion having a first end and a second end; and

at least two tabs extending radially outward from the substantially cylindrical body portion, each of the at least two tabs being longitudinally displaced from the first and second ends, each of said tabs being configured for retention within a preformed recess within a vertebral body.

2. (Amended) An intervertebral implant according to claim 1, wherein the at least two tabs [include a first tab and a second tab, the first tab being] are radially spaced approximately 180° about the substantially cylindrical body portion from [the second tab] each other.

20. (Amended) The intervertebral implant according to claim 1[9], wherein the bone or bone-derived implant comprises [is] animal bone.

21. (Amended) The intervertebral implant according to claim 20[19], wherein the bone or bone-derived implant comprises [is] human bone.

22. (Amended) The intervertebral implant according to claim 1[9], wherein the surface of the bone or bone-derived implant is [surface] demineralized.